UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

ROBERT and KAROL AVENDT,

Plaintiffs,

v.

COVIDIEN INC., a Delaware Corporation

Defendant.
_____/

Case No. 11-cv-15538

Paul D. Borman
United States District Judge

Mona K. Majzoub
United States Magistrate Judge

OPINION AND ORDER GRANTING IN PART DEFENDANT'S MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF DR. MICHAEL J. ROSEN (ECF NO. 130) AND SETTING A *DAUBERT* HEARING

This is a product liability action involving Plaintiffs' claim that Defendant Covidien Inc. ("Covidien") manufactured a defectively designed and inadequately tested hernia mesh product, and failed to warn users of the risks of off-label use of the product. Plaintiffs claim that the mesh that was used to repair Robert Avendt's recurrent hernia caused him to develop a chronic nonhealing infected wound that ultimately required extensive surgery and led to the injuries for which Mr. Avendt seeks recovery in this action. Mr. Avendt's wife, Karol Avendt, seeks damages for loss of consortium. Presently before the Court is Covidien's Motion to Limit the Opinions and Testimony of Dr. Michael J. Rosen. (ECF No. 130.) Plaintiffs filed a Response (ECF No. 159) and Covidien filed a Reply (ECF No. 200). The Court held a hearing on December 22, 2015. Post-hearing settlement talks failed to resolve the matter and Covidien's motion is now ripe for decision. For the reasons that follow, the Court GRANTS IN PART the motion to limit Dr. Rosen's testimony and sets a hearing to test certain of Dr. Rosen's proposed opinions under *Daubert v. Merrell Dow*

Pharmaceuticals, 509 U.S. 579, 592 (1993).

INTRODUCTION

This action involves Plaintiffs' claim that Covidien's biological surgical mesh product ("Permacol"), an FDA approved medical device which was implanted in Plaintiff Robert Avendt on December 17, 2008 to repair a third recurrent hernia, was defectively designed, tested, manufactured and/or marketed. Plaintiffs claim that Permacol was defective in its design as a result of a process called crosslinking, that Defendant failed to adequately test Permacol and failed to warn of the potential for Permacol to fail due to its crosslinked design.[1] Plaintiffs claim that the Permacol implanted in Mr. Avendt caused a chronic nonhealing wound that became infected and ultimately required additional surgery, resulting in significant injuries to Mr. Avendt and a loss of consortium to Mr. Avendt's wife. In support of their claims, Plaintiffs offer the testimony of one of Mr. Avendt's treating physicians, Dr. Michael J. Rosen. Defendant now moves to limit Dr. Rosen's

[1] As discussed *infra*, Permacol is a biologic product (a porcine dermis or pigskin) that undergoes a processing called "crosslinking," through which bonds are established between collagen molecules and fibers by exposure to a solution, in the case of Permacol a solution called hexamethylene diisocyanate ("HMDI"), which gives the product different properties compared to non-crosslinked products. Def.'s Mot. Ex. F, June 30, 2015 Deposition of David F. Williams 6:21-24. Permacol is the only product on the market crosslinked through the HMDI process. *Id*. at 38:23-24. Mr. Williams explains that crosslinking increases the stability and therefore durability of the product because the crosslink bonds established between the molecules and the fibrils means that certain enzymes in the body which normally degrade collagen will find it more difficult to breakdown the collagen and therefore the product will be more durable and longer lasting, providing greater control between the properties of the biologic material (the porcine dermis) and the speed at which that material is replaced with human tissue through ingrowth. In contrast to a non-crosslinked biologic, which is quickly remodeled after implantation (a matter of months maybe a year or so) by the natural collagen of the patient, this process is delayed in the crosslinked material so that the product retains its structure for a longer period of time. The advantage of this is that if the remodeling process goes too fast, then there is a period where the material has lost its characteristics and strength too quickly – before the tissue remodeling has really had a chance to take hold. *Id*. at 35:18-36:19. This process varies greatly from patient to patient and will depend on prior surgeries and on comorbidities, such as obesity and diabetes, of the patient. *Id*. at 36:20-25.

testimony at trial.

I. BACKGROUND

A. Dr. Rosen's Deposition Testimony

Dr. Rosen, a specialist in hernia repair, did not provide a Fed. R. Civ. P. 26(a)(2)(B) written report in this case. (Def.'s Mot. Ex. I, May 11, 2015 Deposition of Michael J. Rosen, M.D. 11:11-13.) His testimony is offered as a treating physician with expertise in the area of abdominal wall reconstruction and specifically hernia repairs. Plaintiffs have filed an expert disclosure pursuant to Fed. R. Civ. P. 26(a)(2)(C) on his behalf. *Id*. at 30:22-24. (Pls.' Resp. Ex. G, Plaintiffs' Fed. R. Civ. P. 26(a)(2)(C) Supplemental Disclosure.) That disclosure, a three-page document prepared by Plaintiffs' counsel and not prepared or signed by Dr. Rosen, contains five unnumbered paragraphs and attaches no supporting documentation. Dr. Rosen is the President of the American Hernia Society and oversaw the publication of a book about hernia repairs entitled "The Atlas of Abdominal Wall Repair," published in 2011. *Id*. at 14:12-21, 15:6-11. As an editor of the book, Dr. Rosen was not responsible for providing content but rather chose individuals he deemed to be "leaders in the field and then ultimately let them write what they want[ed]." *Id*. Dr. Rosen has spoken and trained on the subject of hernia repair utilizing various types of mesh, both synthetic and biologic. *Id*. at 37:1-25, 39:18-40:16. His name appears as a co-author on peer reviewed articles on the topic of complications in the implantation of biologic mesh. *See* Pls.' Resp. Exs. C, S.

Eighty percent of Dr. Rosen's practice is hernia repairs. He uses both synthetic and biologic mesh but "favor[s] synthetic meshes for the vast majority of hernias" he performs. Rosen Dep. 41:4-12. He is currently the Principal Investigator of an FDA monitored study comparing synthetic and biologic mesh. *Id*. at 41:15-18. Outside of the trial, in his clinical practice, he uses biologic mesh

less than 2 percent of the time. *Id*. at 41:18-20. When he uses biologic mesh, he uses Strattice biologic mesh and has never used Permacol. *Id*. at 41:21-25.

Dr. Rosen identified obesity and diabetes as factors that predispose a patient to develop an incisional hernia and to have complications with wound healing. *Id*. at 43:22-44:2. Dr. Rosen testified that the success of most hernia operations comes down to good wound healing. Poor wound healing can affect the recurrence of hernias – patients with poor wound healing will have an increased incidence of recurrence. *Id*. at 46:17-47:11. Poorly controlled diabetes also increases the risk of recurrence of hernias due to the body's inability to produce good collagen to form scar tissue. *Id*. at 49:2-16. Also, the risk of recurrence increases with each recurrence – as much as 40-50% following a third repair. *Id*. at 50:19-51:18. "Once you have a failed hernia, unless things change in some meaningful way, it's a vicious cycle." *Id*. at 50:15-18.

The Covidien synthetic mesh (not at issue in this case) is polyester and the BARD synthetic mesh is polypropylene. Dr. Rosen prefers polypropylene for open procedures. *Id*. at 56:17-57:24. For a biologic mesh, the Cleveland Clinic, with which he is now affiliated, was using Permacol up until approximately 2013 but is switching over to Strattice, which is a pigskin biologic, non-crosslinked mesh. *Id*. at 58:15-59:9. Permacol biologic is also pigskin, but is crosslinked. Both have their selling points. *Id*. at 60:23-61:13. According to Dr. Rosen, the processing of the pigskin biologics is "proprietary" and there is "very little" in the way of clinical trial information available. *Id*. at 60:15-22. There is a lot of debate about which mesh is the best, and the ideal mesh has not been found, but "less than ideal meshes have been revealed." *Id*. at 62:8-22.

Dr. Rosen reviewed the Permacol Instruction-For-Use ("IFU") document for a paper that he wrote and recalls that it contained a warning or a contraindication in the presence of infection or

contamination which he feels is not what a surgeon wants to hear when they are "reaching for a biologic mesh." *Id*. at 63:19-21; Def.'s Mot. Ex. E, IFU. Dr. Rosen explained that use of the term "infected" is a bit misleading and prefers to refer to the Centers for Disease Control ("CDC") "crystal clear guidelines" for the four wound classes: Class I (clean), Class II (clean contaminated), Class III (contaminated) and Class IV (dirty). *Id*. at 70:1-5. Class I (clean) wounds are those in which there has been no contamination or potential for contamination; Class II (clean contaminated) wounds are those in which there has been no observable contamination but there has been a "breach" that creates the possibility of contamination; Class III (contaminated) wounds are those in which contamination has been observed to be present; and Class IV (dirty or infected) wounds are those in which the presence of an overt infection has been detected.

All mesh on the market, both biologic and synthetic, is FDA approved for use in a "clean" Class I wound for "reenforcement where soft tissue weakness exists," to quote the Permacol IFU terminology. *Id*. at 67:3-9. No mesh, biologic or synthetic, is approved for use in a Class II-IV wound. When bacteria get on these mesh materials, "there is a concern that collagenations in the bacteria can break down the mesh and affect its long-term performance." *Id*. at 67:9-13. While every company would like to be able to market a mesh with the indication for use in a contaminated field, "no company is going to take the risk of a randomized controlled trial that might disprove that their mesh is worthwhile and spend millions of dollars." *Id*. at 68:23-69:2. So, no mesh on the market is FDA "approved" for use in anything other than a Class I wound, but biologic mesh is "believed" to tolerate an infected environment better than a synthetic mesh. Despite the fact that no mesh is FDA approved for use in such wound environments, surgeons exercise their independent judgment and do utilize various mesh products in non-Class I wounds (an "off-label" use) on a

regular basis.

Dr. Rosen has been the Principal Investigator on trials involving synthetic and biologic mesh products. *Id*. at 41:15-18, 65:18-66:3. In 2007 or 2008, the FDA tried to start a trial, which Rosen reviewed, to remove infected mesh and replace it with Permacol but the consensus was that it would probably fail so the trial never got going. *Id*. at 67:18-25. Because such a trial was "beyond the scope of what the FDA requires," companies decided not to take the business/financial risk of undertaking the trial. *Id*. at 68:6-9. At the time of his deposition, Dr. Rosen was involved in a randomized trial for Covidien comparing synthetic to biologic mesh in clean and clean contaminated wounds. *Id*. at 70:4-11. If in his practice he was faced with a patient with a Class II or III wound, he would have a conversation with the patient about the risks and benefits of both synthetic and biologic, explaining that the synthetic will have a lower recurrence rate but the biologic, although having a higher long term recurrence rate, "potentially can handle an infection better." *Id*. at 71:6-25. But he would never use a crosslinked mesh in a Class II or III wound.

While at University Hospital in Cleveland in 2007-2009, Dr. Rosen conducted basic science work in his lab on all different types of meshes to determine how they respond to the presence of contamination. *Id*. at 72:4-11. The determinants are multi-factorial and include the size of the pores, the weight of the material, and the type of material. *Id*. at 73:7-9. When you place a mesh into a contaminated field, i.e. anything but a Class I wound, "it basically becomes a race for ingrowth into the tissue or bacterial coating of the material and then infection, puss [sic], biofilms." *Id*. at 73:17-22. So, the quicker things "ingrow," the more resistant the site will be to bacterial colonization that propagates the infection. *Id*. at 73:22-25. In Dr. Rosen's opinion, the best synthetic product for a contaminated wound would be a large pore polypropylene and the best

biologic would be a "non-crosslinked porcine dermis," (pigskin). *Id*. at 74:18-75:4. For patients who are very infection averse and more tolerant of a recurrence, he might suggest the biologic and for those who are averse to a recurrence but will risk the infection, he would suggest the large pore polypropylene synthetic. *Id*. at 75:12-23.

While Dr. Rosen has been involved in several clinical trials involving mesh products, he has not studied the underlying design of the Permacol product in terms of the methods, such as crosslinking, employed to produce the mesh. *Id*. at 78:20-79:8. Indeed, although Dr. Rosen testified that he doesn't use Permacol because "he [doesn't] like crosslinking," Dr. Rosen could not explain the process involved in crosslinking and could not identify the difference between the biologic mesh that he uses (Strattice) and the Permacol biologic mesh other than the fact that the Strattice product is not crosslinked. *Id*. at 83:8-84:1. Nor does Dr. Rosen profess to have expertise in the area of human immune response to the various mesh materials, although he is aware of the data resulting from mostly animal-based studies. *Id*. at 80:23-82:8. His expertise is in the clinical aspects of the competing types of mesh, a subject that is today, still very much under study. He describes the current competing clinical observations as follows:

> Q: So what do you tell your patients about the risks and benefits with your synthetic option versus your biologic option?
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> A: Well, I think with the large pour [sic] polypropylene mesh, we talk about the fact that it tends to be fairly durable, to have a lower recurrence rate and in our clinical experience up to date, it seems to be fairly resistant to infection and will still incorporate in the face of infection. But the point of the study is that we're trying to figure out if that's actually true.
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> The biologic mesh tends to be less durable long term, because you have to lay down your own scar tissues and things like that, so recurrence rates can be a little bit higher. But if you were to get an infection, it's often something we can treat through and don't need to reoperate and it might dissolve and go away and you'd be left with a recurrence but not a chronic infection problem.

Rosen Dep. at 86:18-87:13.

Dr. Rosen concedes that he "was not the scientist who vetted" Permacol but he believed that Covidien was trying to find a "sweet spot" between a heavily crosslinked biologic mesh (for example Collamend) and a non-crosslinked biologic mesh (Strattice for example) – trying the achieve a balance between durability and "early cellular filtration" that permits early integration which theoretically allows faster resolution of an infection. *Id*. at 132:7-133:15. Dr. Rosen is "not a big biologic mesh user," and "doesn't keep up" with how widely crosslinked mesh is used, but he testified that up until about 2013, his colleagues at the Cleveland Clinic were using Permacol crosslinked biologic mesh. *Id*. 134:1-135:5, 136:2-10.

Dr. Rosen performed the initial portion of the surgical procedure on Mr. Avendt on January 28, 2010. His role was to go in, get down all the scar tissue, remove the bowel adhesions, remove any infected mesh and then leave a hole where they were going to try to reconstruct the herniated area with just a flap, not using any other material or mesh, to try to cure his infection, which was a Class IV wound on the date of surgery. *Id*. at 98:17-99:12, 101:20-22. Dr. Rosen completed his portion of the procedure and was followed immediately by Dr. Salgado, who took skin, fascia and muscle from Mr. Avendt's thighs to create the flap for the abdominal repair. *Id*. at 100:12-101:1. Dr. Salgado placed drains at the surgical site and closed the wound. *Id*. at 101:8-19.

Six months following the surgery by Drs. Rosen and Salgado, Mr. Avendt had developed a recurrence of his hernia and an infection on his right leg where Dr. Salgado had removed the skin for the abdominal flap. *Id*. at 105:2-106:20. Mr. Avendt reported to Dr. Rosen on November 5, 2010, that his hernia was fairly asymptomatic but he was having a lot of weakness and pain in his leg that Dr. Salgado had operated on, and difficulty getting around. *Id*. at 107:9-108:5. Dr. Rosen

opines that the hernia recurrence following the surgery performed by Dr. Rosen and Dr. Salgado was due to the fact that the "defect was so big after what had happened to him in the past and in the presence of a Class 4 wound" the ultimate goal was to get the wound to heal and accept a fairly high chance of a recurrence. *Id*. at 113:18-25.

Dr. Rosen recalls discussing generally with Mr. Avendt the issues about infection and recurrence with hernia mesh repairs but did not tell Mr. Avendt that Permacol was a defective product and never wrote to the FDA or told anyone in his hospital that Mr. Avendt had a defective mesh. *Id*. at 116:17-117:21. Dr. Rosen did not recall whether he looked into the pathology of Mr. Avendt's removed Permacol mesh or if he included Mr. Avendt's case in any of his case studies. *Id*. at 119:13-121:12.

Today, Dr. Rosen is of the opinion that in 2009, Permacol was not a reasonably safe product based on the data then available which indicated that a crosslinked material would not behave like a biologic mesh and, in 2009, Dr. Rosen would not have chosen a crosslinked biologic material. *Id*. at 127:19-25. Although not "the scientist who vetted it," Dr. Rosen opines that in looking at the Permacol mesh the problem was that "they decided to heavily crosslink that material" and consequently made it tougher to break down and more of a barrier to ingrowth. *Id*. at 132:7-133:15. Dr. Rosen opines that every company knows that their biologic mesh product 90% of the time is being put in a Class II or III wound situation and even though the FDA does not require biologic mesh to specifically have clearance for use in a Class II or III wound, a surgeon asking for a biologic mesh product would reasonably assume that the product was designed to perform in that wound class. *Id*. at 142:11-144:22. Dr. Rosen opines that if Mr. Avendt had received a non-crosslinked biologic mesh, he likely would have had a recurrence but it would have been in a clean field. *Id*.

at 148:12-149:2. With a non-crosslinked mesh, the body would have cleared the infection and he would have had a recurrence that could have been repaired with a synthetic mesh. "But because of the size of the hernia, the complexity of the hernia and the active infection in a Class IV wound, that's when essentially all of his reconstructive options were burned due to the chronic, ongoing infection with the big hernia." *Id*. at 149:2-7. Because the Permacol mesh was crosslinked, "it behaved like a synthetic mesh and was unable to be cleared. That's why it was an ongoing infection when I saw him." *Id*. at 149:18-21.

Dr. Rosen is clear that he does not know, and does not profess to know, the scientific process by which the Permacol mesh is crosslinked and is not sure if he has ever even examined a Permacol mesh although he knows it smells like cat urine. He is not a material scientist or a biomedical engineer although he has collaborated with many such experts on his papers. *Id*. at 151:24-152:18, 164:4-165:10. He has no understanding of the immunological response to crosslinked mesh and concedes that this is not his area of expertise. *Id*. at 80:23-82:8. In essence, Dr. Rosen is of the opinion that Covidien knew that Permacol was being used in situations for which it was contraindicated, i.e. off-label in Class II or III wounds, and should have studied further whether it was safe in those off-label applications. *Id*. at 151:12-23.

Dr. Rosen testified that he supports his conclusions about the cause of Mr. Avendt's injuries by (1) his discovery during Mr. Avendt's surgery of the pieces of Permacol mesh in an infected environment and (2) his clinical experience which has taught him that the only time biologic mesh doesn't go away is when it is crosslinked and "just sits there" and doesn't dissolve. *Id*. at 154:7-155:16. Dr. Rosen testified that he would use a Permacol mesh only in a situation in which a synthetic mesh would be indicated, i.e. in a clean or Class I wound. *Id*. at 157:1-11. Dr. Rosen

testified that at the Cleveland Clinic, 100% of the use of biologic mesh is off-label, outside of its indication, because no mesh is indicated for use in a Class II or III wound. But Dr. Rosen would never elect to use a crosslinked mesh in such a situation. *Id*. at 157:11-22. His only criticism of the Permacol mesh is that it is crosslinked and in his clinical experience, he has never seen a mesh sitting in pus outside of crosslinked material. *Id*. at 167:19-24. He has never taken care of a case of a non-crosslinked biologic mesh where he has had to go back in and remove an infected piece of mesh. The non-crosslinked biologic mesh will dissolve and clear in the face of infection and at most you are left with a recurrence. *Id*. at 169:14-18. Dr. Rosen testified that he has reviewed articles that indicate that other non-crosslinked biologic mesh products are safe in Class II or III wounds, but he has never seen such a statement regarding a Permacol mesh. *Id*. at 171:11-172:16.

Dr. Rosen summarized his opinion that the crosslinking of the Permacol mesh caused Mr. Avendt's injuries:

> Q: So in terms of what was your methodology in coming to your conclusion of the case that it was the crosslinking that –
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> A: Sure. So my hypothesis was, he had a chronic draining sinus because there was a piece of foreign material in there, Permacol. So my observation was that the wound did not heal for a year. In my experience in maybe managing 2 to 3,000 of these cases, typically when wounds don't heal, there's some remaining foreign body that the body cannot clear.
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> So when we operated on him and performed the experiment, we drilled down and actually were able to observe and document unincorporated Permacol crosslinked mesh sitting in a bed of puss [sic] and granulation tissue due to ongoing nonhealing. And when we removed it all, you know, my conclusion, even in the setting of contamination, the wound healed. So to me that's conclusive, that for one year the wound didn't heal, you take out the one thing and everything heals from an infectious standpoint, to me, that's pretty good scientific evidence that it's conclusive.
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> * * *

Q: Well, if he had the infection before the Permacol came in, how would that change your opinion?

A: Well, if he had – I mean, would I – I would still say that the crosslinked material was put in an infected field. Usually it should have – if it continued with an infection, it should have broken down and gone away; and the reason it didn't was because it was crosslinked. So I don't think it would necessarily change my opinion.

Q: When you removed the Permacol, did you take out the full piece of Permacol in one piece or was it in several pieces?

A: It was in several pieces.

Q: What does that indicate to you?

A: That it was in several pieces.

* * *

Q: Does the fact that it was in several pieces show that it was breaking down or had broken down?

A: Possibly, yes.

Rosen Dep. 174:17-175:16, 176:7-177:2.

When asked his understanding of his role in testifying in this matter, Dr. Rosen responded:

Q: Do you understand that you're only designated as a treating doctor? Have you had any conversation with the plaintiff's lawyers about that?

A: I asked like what exactly my role is in this and I think they said I'm like a hybrid, so where I was the treating doctor and obviously I can provide expert testimony just because of my clinical experience.

Q: And that's what you expect to do at trial?

A: Sure.

Q: Your opinions about crosslinking were not formed because of Mr. Avendt; they were formed outside of that, correct?

A: Well, no, they were not formed exclusively because of him. They were formed because of my clinical experience in the lab and treating patients with complications related to crosslinked materials.

Q: Was that before 2009 or after 2009?

A: I think it started before and has continued to date.

Rosen Dep. 190:11-191:9.

B. Dr. Rosen's 26(a)(2)(C) Disclosure and Magistrate Judge Majzoub's December 20, 2014 Order

On April 9, 2014, Defendant filed a motion to strike Dr. Rosen's Fed. R. Civ. P. 26(a)(2)(C) expert disclosure on the basis that his proposed testimony and opinions went far beyond the scope of his treatment and care of Mr. Avendt and Dr. Rosen had not filed a written expert report as required under Rule 26(a)(2)(B). (ECF No. 87, Def.'s Mot. to Strike.) Magistrate Judge Majzoub, in an Order issued on December 20, 2014 (to which Defendant did not object), concluded that Dr. Rosen is a treating physician who was not required to file an expert report under Fed. R. Civ. P. 26(a)(2)(B), and further concluded that Plaintiffs satisfied the requirements of Fed. R. Civ. P. 26(a)(2) by supplying a disclosure for Dr. Rosen that comports with 26(a)(2)(C). (ECF No. 95, 12/10/14 Order.) Magistrate Judge Majzoub's 12/10/14 Order does not purport to rule on the appropriate scope or ultimate admissibility of Dr. Rosen's testimony and opinions. Indeed, at the time that Magistrate Judge Majzoub issued her Order, Dr. Rosen had not even been deposed and thus the scope of his expertise and the course of his treatment of Dr. Avendt were not fully known. Thus, this Court is not constrained by Magistrate Judge Majzoub's Order in ruling on the Defendant's motion to exclude portions of Dr. Rosen's opinion and testimony at trial. *See Lettieri v. Equant Inc.*, 478 F.3d 640, 652 (4th Cir. 2007) ("[T]he law of the case doctrine does not prevent a district judge from implicitly reconsidering a magistrate judge's earlier ruling in the same case.") (citing *Hill v. BASF Wyandotte Corp.*, 696 F.2d 287, 290 n. 3 (4th Cir. 1982)). *See also Pepper v. United States*, 562 U.S. 476, 506-07 (2011) (noting that the law of the case doctrine "directs a

court's discretion, it does not limit the tribunal's power" and "does not apply if the court is convinced that [its prior decision] is clearly erroneous and would work a manifest injustice") (internal quotation marks and citations omitted).

Plaintiffs argued to Magistrate Judge Majzoub, and reiterated in argument to this Court in response to Covidien's motion to limit Dr. Rosen's testimony, that as a result of the 2010 Amendments to Fed. R. Civ. P. 26(a)(2), Dr. Rosen, a treating physician, did not have to file a Rule 26(a)(2)(B) Report, and therefore Plaintiffs' Rule 26(a)(2)(C) disclosure was sufficient. Much has now been written about the correct interpretation of the addition of Rule 26(a)(2)(C) to the Federal Rules of Civil Procedure in 2010, and this Court has now exhaustively reviewed both the commentary and the case law and concludes that Plaintiffs are mistaken in their understanding of the impact of Rule 26(a)(2)(C) on the law governing the filing of expert reports. As discussed below, this Court is of the view that in adding the expert disclosure provision in 26(a)(2)(C), the drafters did not intend to absolve *all* treating physicians, simply by virtue of their *status* as treating physicians, of the obligation of filing an expert report under Rule 26(a)(2)(B). As was the case before the 2010 Amendments, if a treating physician is going to offer expert testimony that goes beyond the diagnosis and treatment of the patient and purports to opine on causation that was not determined as part of the treating relationship, that treating physician must still file a full blown expert report under 26(a)(2)(B).

Fed. R. Civ. P. 26(a)(2)(A) provides:

> *In General*. In addition to the disclosures required by Rule 26(a)(1), a party must disclose to the other parties the identity of any witness it may use at trial to present evidence under Federal Rule of Evidence 702, 703, or 705 [relating to the testimony of experts].

Fed. R. Civ. P. 26(a)(2)(A) (alteration added).

Rule 26(a)(2)(B) provides:

> *Witnesses Who Must Provide a Written Report*. Unless otherwise stipulated or ordered by the court, this disclosure must be accompanied by a written report – prepared and signed by the witness – if the witness is one retained or specially employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony. The report must contain:
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> (i) a complete statement of all opinions the witness will express and the basis and reasons for them;
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> (ii) the facts or data considered by the witness in forming them;
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> (iii) any exhibits that will be used to summarize or support them;
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> (iv) the witness's qualifications, including a list of all publications authored in the previous 10 years;
>
> (v) a list of all other cases in which, during the previous 4 years, the witness testified as an expert at trial or by deposition; and
>
> (vi) a statement of the compensation to be paid for the study and testimony in the case.

Fed. R. Civ. P. 26(a)(2)(B).

Rule 26(a)(2) was amended in 2010 adding subsection 26(a)(2)(C), which provides:

> *Witnesses Who Do Not Provide a Written Report.* Unless otherwise stipulated or ordered by the court, if the witness is not required to provide a written report, this disclosure must state:
>
> > (i) the subject matter on which the witness is expected to present evidence under Federal Rule of Evidence 702, 703, or 705; and
> >
> > (ii) a summary of the facts and opinions to which the witness is expected to testify.

Fed. R. Civ. P. 26(a)(2)(C).

The Advisory Committee Notes accompanying the 2010 Amendments explain that the changes adding subsection 26(a)(2)(C) are intended to "resolve[] a tension that has sometimes

prompted courts to require reports under Rule 26(a)(2)(B) even from witnesses exempted from the report requirement. . . . A witness who is not required to provide a report under Rule 26(a)(2)(B) may both testify as a fact witness and also provide expert testimony under Evidence Rule 702, 703, or 705. Frequent examples include physicians or other health care professionals . . . who do not regularly provide expert testimony." Rule 26 Advisory Committee Notes, 2010 Amendment, Subdivision (a)(2)(C).

The following lengthy excerpt from the Federal Rules of Civil Procedure, Rules and Commentary, explains with great clarity the rationale and impact of Rule 26(a)(2)(C), and this interpretation has been echoed by many courts:

> Treating physicians. Treating physicians present two expert disclosure issues. The first is whether the treating physician must be disclosed as an expert under Rule 26(a)(2)(A). In one respect, treating physicians are fact witnesses who will testify as first-hand participants in the diagnosis and treatment of the plaintiff. But the diagnosis and treatment provided were almost certainly informed by the physician's specialized training and knowledge. For this reason, courts consistently hold that treating physicians ordinarily must be disclosed as expert witnesses (or have their testimony limited to lay fact observations).
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> The second issue is what additional information must be supplied for treating physicians. Under the scheme adopted in December 2010, the question is whether it is sufficient to submit Rule 26(a)(2)(C) summary disclosures for treating physicians or whether they must submit formal expert reports under Rule 26(a)(2)(B). Under the case law that preceded the December 2010 amendments, courts generally did not view treating physicians as having been retained or specially employed to give expert testimony—and therefore did not require reports—so long as their opinions were formed as a part of the patient's treatment and diagnosis. However, courts also held that if the treating physician was going to give opinions formed outside the scope of the patient's treatment and diagnosis, then the treating physician had to file an expert report as to this further testimony or it was subject to exclusion.
>
> *The distinction drawn in these precedents would appear to still be good law.* The Advisory Committee Notes accompanying the new summary disclosure provisions of Rule 26(a)(2)(C) affirm the idea that treating physicians generally do not have to file formal expert reports. This is because treating physicians that limit their opinions

> to those developed during diagnosis and treatment are not considered to be "retained or specially employed" as experts in the case. But there is no reason to conclude that Rule 26(a)(2)(C) was intended to allow treating physicians to give expert opinions that go beyond the scope of treatment and diagnosis without having to prepare a report with respect to those further opinions.
>
> In summary, the disclosures that must be made for a treating physician depend on the nature of the testimony he or she will give. Unless the treating physician is going to be limited to testifying about facts in a lay person capacity, the physician must be disclosed as an expert and must provide either the summary disclosures or an expert report. Whether the treating physician must file a written report or is subject only to summary disclosures depends on the role of the expert. If the treating physician's expert opinions stay within the scope of treatment and diagnosis, then the physician would not be considered "retained" to provide expert testimony and only summary disclosures would be needed. But if a treating physician is going to offer opinions formed outside the course of treatment and diagnosis, then as to those further opinions the physician is being used in a "retained expert" role and the Rule 26(a)(2)(B)'s report requirement will apply to the extent of that further testimony. It is not sufficient for the summary disclosures to mention that the treating physician is going to offer these additional expert opinions.
>
> The types of disclosures made will then determine the scope of testimony actually allowed. Treating physicians disclosed only as lay witnesses may testify only to lay facts. Treating physicians for whom summary disclosures are provided may opine on matters relating to treatment and diagnosis. If the treating physician files an expert report, then the treating physician may testify as a retained expert to matters that go beyond treatment and diagnosis.

1 Federal Rules of Civil Procedure, Rules and Commentary Rule 26 (at footnotes (81-85)) (text of footnotes omitted) (emphasis added). Thus, the substance of a treating physician's testimony, and not his or her status as a treating physician, determine whether a Rule 26(a)(2)(B) report will be required or whether a Rule 26(a)(2)(C) disclosure will suffice. In making this call, the distinction made in pre-2010 case law, between treating physicians who opine only on matters relating to their treatment and diagnosis on the one hand and treating physicians who offer opinions that fall outside the scope of the treating relationship on the other, continues to be determinative.

Several courts have echoed this interpretation of the 2010 Amendment, concluding that in adding subsection 26(a)(2)(C), the drafters did not intend to absolve *all* treating physicians, simply by virtue of their status as a treating physician, from filing a full-blown expert report under 26(a)(2)(B) when their testimony strays beyond the scope of treatment and diagnosis and into the realm of a "retained expert:"

> Courts in this Circuit and others have noted that the 2010 amendments, which added a heightened disclosure standard for non-specially retained experts, "did not alter who was required to file an expert report under the rule 26(a)(2)(B)." *Call v. City of Riverside*, No. 3:13–CV–133, 2014 WL 2048194, at *2 (S.D.Ohio May 19, 2014) (citing *Coleman v. Am. Family Mut. Ins. Co.*, 274 F.R.D. 641, 645 (N.D. Ind. 2011); and *Kondragunta v. Ace Doran Hauling & Rigging Co.*, No. 1:11–cv–1094, 2013 WL 1189493, at *12 (N.D. Ga. Mar. 21, 2013). Such a determination was, and remains, dependent on "the scope, substance, and source of the intended testimony-not on whether the witness is being compensated." *Ulbrick v. UPR Products, Inc.*, No. 08–13764, 2011 WL 500034, at *4 (E.D. Mich. Feb.8, 2011) (noting that a non-specially retained expert mechanic's opinions fell under subsection B, not C, because his opinions were formed to determine the cause of a car accident, not to repair the vehicle, and thus "were presumably formed as a result of a process that any expert witness would undertake; namely, an 'after-the-fact' examination of the vehicle in question"). Thus, prior to 2010, a party that thought the Rule 26(a)(2)(B) reporting requirements should apply to a hybrid witness testifying both to fact and opinion, but who was not specially retained, had to bring a challenge to the opposing party's failure to provide a Rule 26(a) (2)(B) report, and the same is true after the amendment. *See Davis v. GEO Grp.*, No. 10–CV–02229–WJM–KMT, 2012 WL 882405, at *2 (D. Colo. Mar. 15, 2012) (finding that historically the party moving to strike the witness bears the initial burden of showing that the disclosing party failed to produce a written report under Rule 26(a) (2)(B); then, the burden shifts to the disclosing party to demonstrate ... no report was required.").

Little Hocking Water Ass'n, Inc. v. E.I. DuPont de Nemours and Co., No. 09-cv-1081, 2015 WL 1105840, at *12 (S.D. Ohio March 11, 2015). *See also Brunswick v. Menard, Inc.*, No. 11-cv-247, 2013 WL 5291965, at *3-4 (N.D. Ind. Sept. 19, 2013) (adopting Report and Recommendation) (noting that the 2010 Amendments did not alter who was required to file a report under 26(a)(2)(B) and that the determination of whether a treating physician must file a disclosure under (C) or a report

under (B) depends upon "the breadth of their testimony," requiring a "full expert report" if "a treating physician intends to testify beyond his observations") (citing Meyers *v. Nat'l R.R. Passenger Corp*., 619 F.3d 729, 734-35 (7th Cir. 2010) (a pre-2010 Amendment case holding that: "[A] treating physician who is offered to provide expert testimony as to the cause of plaintiff's injury, but who did not make that determination in the course of providing treatment, should be deemed to be one 'retained or specially employed to provide expert testimony in the case,' and thus is required to submit an expert report in accordance with Rule 26(a)(2)."); *Tanganeka v. UAW Int'l*, No. 15-cv-10525, 2015 WL 6156968, at *1 (E.D. Mich. Oct. 19, 2015) (noting the more relaxed expert disclosure requirement of 26(a)(2)(C) but noting that testimony that goes beyond "the permissive core on issues pertaining to treatment" would require an expert report under 26(a)(2)(B)); *Laslovich v. State Farm Fire and Cas. Co*., 307 F.R.D. 533, 536 (D. Mont. May 14, 2015) (noting that expert reports under 26(a)(2)(B) are required, and 26(a)(2)(C) disclosures are insufficient, for treating physicians who offer opinions that go beyond the scope of treatment); *Blakely v. Safeco Ins. Co.*, No. 13-cv-796, 2014 WL 1118071, at *2-3 (M.D. Fla. Mar. 20, 2014) (observing that in determining whether a Rule 26(a)(2)(B) report is required, the label of "treating physician" is irrelevant and holding that a "physician who supplies an opinion procured directly from treatment is not subject to the expert witness disclosure requirements in Rule 26(a)(2)(B). . . . [b]ut if a health care professional is asked to give any additional opinions, beyond those procured directly from treatment, then for those additional opinions to be admissible, Plaintiff must first provide the full written disclosures required by Rule 26(a)(2)(B)."); *In re World Trade Center Lower Manhattan Disaster Site Litig.*, No. 21-mc-102, 2014 WL 5757713, at *4-5 (S.D.N.Y. Nov. 5, 2014) (requiring plaintiffs' treating physicians to file expert reports under 26(a)(2)(B) where their opinions stray

outside the context of the plaintiffs' medical records and course of treatment and therefore cannot be gleaned from a review of the medical records); *Hinkle v. Ford Motor Co*., No. 11-cv-24, 2013 WL 1992834, at *5 n. 4 (E.D. Ky. May 13, 2013) (discussing the 2010 Amendments and Rule 26(a)(2)(C) and concluding that treating physicians who intend to offer testimony beyond the scope of their own diagnosis and treatment are still required to file full expert reports under 26(a)(2)(B) as to testimony that testimony); *Beane v. Utility Trailer Mfg. Co*., No. 10-cv-781, 2013 WL 1344763, at *3 (W.D. La. Feb. 25, 2013) (noting that post-2010 amendments, "the distinction between a 26(a)(2)(B) expert and a 26(a)(2)(C) expert is that 26(a)(2)(C)'s experts' conclusions and opinions arise from firsthand knowledge of activities they were personally involved in before the commencement of the lawsuit, not conclusions they formed because they were recruited to testify as an expert after-the-fact."); *Kondragunta v. Ace Doran Hauling & Rigging Co*., No. 11-cv-01094, 2013 WL 1189493, at *10-12 (N.D. Ga. March 21, 2013) (concluding that "prior caselaw concerning the standard for when a hybrid expert, such as a treating physician, should be deemed a full-blow Subsection B expert has not been abrogated by the newly-added text in Rule 26(a)(2)(C)," and requiring 26(a)(2)(C) disclosures "if a physician's opinion regarding causation or any other matter was formed and based on observations made during the course of treatment" and a 26(a)(2)(B) report where "the physician's opinion was based on facts gathered outside the course of treatment"); *In re Denture Cream Pdcts. Liab. Litig*., No. 09-mdl-2051, 2012 WL 5199597, at *4 (S.D. Fla. Oct. 22, 2012) (analyzing the 2010 Amendment and holding: "When a treating physician testifies regarding opinions formed and based upon observations made during the course of treatment, the treating physician need not produce a Rule 26(a)(2)(B) report. By contrast, treating physicians offering opinions beyond those arising from treatment are experts from whom full Rule

26(a)(2)(B) reports are required.") (citations omitted); *Walti v. Toys R U.S.*, No. 10-C-2116, 2011 WL 3876907, at *6 (N.D. Ill. Aug. 31, 2011) (observing that, even after the 2010 Amendments, "a treating physician who provides an expert opinion regarding causation is required to provide an expert report pursuant to Rule 26(a)(2)(B) if that opinion was not previously determined during the course of treatment").

To summarize, following the 2010 Amendments and the addition of 26(a)(2)(C)'s relaxed "disclosure requirement" for certain testimony of a treating physician, district courts in this circuit and elsewhere continue to observe the restrictions on treating physician testimony first articulated in *Fielden v. CSX Transp., Inc.*, 482 F.3d 866, 871 (6th Cir. 2007): that a treating physician who endeavors to provide expert testimony that goes beyond the "permissive core on issues pertaining to treatment, based on what he or she learned through actual treatment and from the plaintiff's records up to and including that treatment," must still file an expert report that conforms to the requirements of 26(a)(2)(B). In determining whether a Rule 26(a)(2)(B) report is required, Plaintiffs bear the burden of demonstrating that a full-blown expert report is not required and "the label of "treating physician" is irrelevant; instead, the determination turns on the substance of the physician's testimony." *In re Denture Cream*, 2012 WL 5199597, at *4. A treating physician "may be subject to Rule 26(a)(2)(C) as to portions of his or her testimony and may be deemed a retained or specially employed expert who is subject to Rule 26(a)(2)(B) as to other portions." *Goodman v. Staples the Office Superstore, LLC*, 644 F.3d 817, 826 (9th Cir. 2011).

In this case, Defendant did bring a challenge to Plaintiffs' failure to file a Rule 26(a)(2)(B) Report with regard to Dr. Rosen's proffered opinions in this case. Magistrate Judge Majzoub based her decision that Plaintiffs had satisfied Rule 26(a)(2) by filing a Rule 26(a)(2)(C) disclosure on

Plaintiffs' five-paragraph disclosure regarding Dr. Rosen's expected testimony and Plaintiffs' representation that "Dr. Rosen formed his opinions regarding the cause of Plaintiff's injuries during the course of treatment" and that his testimony was based on "his personal knowledge of Permacol prior to Plaintiff's surgery and his aforementioned expertise." ECF No. 95, 12/20/14 Order. Although the Court does not doubt that Plaintiffs' Rule 26(a)(2)(C) disclosure was issued in the good faith belief (or perhaps hope) that Dr. Rosen would testify in accordance with the disclosure, Dr. Rosen's subsequent deposition revealed that Plaintiffs' good faith belief as to the scope and substance of his anticipated opinion was misplaced.

While certain of Dr. Rosen's opinions that Plaintiff seeks to offer in this case were adequately disclosed in Plaintiffs' 26(a)(2)(C) disclosure and are not excludable for failure to file a Rule 26(a)(2)(B) report, other of Dr. Rosen's opinions go well beyond the scope of his care and treatment of Mr. Avendt and required the filing of a formal Rule 26(a)(2)(B) report. The remedy for the failure to file the required expert report is exclusion of the opinion testimony, unless the Plaintiffs can establish that the insufficiency in their disclosures was either substantially justified or harmless. *See* Fed. R. Civ. P. 37(c)(1), providing that if a party fails to comply with Rule 26, "the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or harmless."

Reviewing Plaintiffs' Supplemental Disclosures, (ECF No. 159, Pl.'s Resp. Ex. G), the Court concludes that a Rule 26(a)(2)(C) disclosure was sufficient with regard to the following proposed opinions contained in paragraph one of Plaintiffs' disclosure: the facts and circumstances surrounding the need for removal of Permacol and the abdominal reconstruction surgery, the nature and extent of Robert Avendt's condition upon presenting for surgery [and] his diagnosis of Robert

Avendt's injuries, and "medical causation," but only to the extent that Plaintiffs can establish that such opinion was formed for purposes of, and within the scope of, his care and treatment of Mr. Avendt. There is no evidence that Dr. Rosen formed an opinion regarding Mr. Avendt's future prognosis at the time of treatment and, despite treating Plaintiff in 2010, he has not seen Mr. Avendt in the five years following his surgery, so that the Rule 26(a)(2)(C) submission was insufficient as to his proposed testimony regarding Mr. Avendt's future prognosis. *See Rea v. Wisconsin Coach Lines, Inc.*, No. 12-1252, 2014 WL 4981803, at *6 (E.D. La. Oct. 3, 2014) (failure to meet with the patient and to review medical records precluded Plaintiff's surgeon from testifying regarding her need for future surgeries.").

Plaintiffs' disclosure also sufficiently disclosed Dr. Rosen's proposed testimony as a treating physician, set forth in paragraph two of the disclosure, regarding: (1) his clinical and surgical experience in abdominal wall repair and hernia surgery that he possessed as of the date of Mr. Avendt's surgery; (2) his opinion that, at the time of Mr. Avendt's January 2010 surgery, scarring had damaged Robert Avendt to the point that Dr. Rosen's best surgical option at the time was to remove the remnants of the Permacol and use an aggressive procedure to repair the damage.

With regard to the opinions proffered in paragraphs three, four and five of the Rule 26(a)(2)(C) disclosure, which relate to matters well outside the scope of Dr. Rosen's care and treatment of Mr. Avendt, the Rule 26(a)(2)(C) disclosure was insufficient and a Rule 26(a)(2)(B) expert report was required. Defendants claim that the inability to depose Dr. Rosen with the benefit of a Rule 26(a)(2)(B) report put them at a significant disadvantage in preparing this case for trial, and Dr. Rosen's deposition testimony appears to bear this claim out. In many instances, Dr. Rosen could not recall at his deposition what published literature supported his opinion, and Covidien's

counsel was unable to prepare to examine Dr. Rosen on what, if anything, he did to test his hypothesis that crosslinking caused Mr. Avendt's injuries. *See, e.g.* Rosen Dep. 141:5-14; 173:11-174:19. Plaintiffs respond that any failure to file a Rule 26(a)(2)(B) report was cured because Defendant's experts were able to review Dr. Rosen's deposition transcript. Although Defendant's experts may have been able to review Dr. Rosen's deposition, without a Rule 26(a)(2)(B) report counsel for Defendant was unable to review with Covidien's own experts Dr. Rosen's opinions and the bases for those opinions in advance of Dr. Rosen's deposition. This is the very prejudice that Rule 26(a)(2)(B) seeks to prevent, particularly in an area of medical specialization and scientific study such as that at issue in this case.

Rule 26(b)(4) provides that depositions of experts who are required to file a Rule 26(a)(2)(B) report are not to be conducted until after the report is provided and the reasons for this are well illustrated here. This requirement enables the opposing party to determine all of the experts' opinions and the bases for those opinions, to review with the expert any exhibits that the expert will rely on to support or summarize his opinions, his qualifications including a comprehensive list of publications authored in the previous 10 years and a statement regarding other testimony and compensation, if any. Covidien had received none of this when they deposed Dr. Rosen, and they were informed only by: (1) Dr. Rosen's brief medical records regarding his care and treatment of Mr. Avendt, none of which referred to crosslinking in any way and none of which disclosed that Dr. Rosen believed that crosslinking of Permacol was the cause of Mr. Avendt's injury, and (2) Plaintiffs' Rule 26(a)(2)(C) disclosure.

There is no question that Covidien was prejudiced by the absence of a Rule 26(a)(2)(B) Report as to much of Dr. Rosen's proposed testimony. On the other hand, Plaintiffs did get an

apparent "green light" from Magistrate Judge Majzoub, although based only upon Plaintiffs' "good faith representations" as to the scope of and bases for Dr. Rosen's expected testimony, which in fact largely overstated Dr. Rosen's "expertise." At the same time, Defendant did have experts of its own with whom to consult regarding the disclosure and did have five months to prepare for Dr. Rosen's deposition, albeit Defendant was still hamstrung by the lack of receiving a full blown expert report from Plaintiffs. Within approximately two and a half months of taking Dr. Rosen's deposition, Defendant filed the motion that is now before the Court to strike the majority of Dr. Rosen's proposed opinions.

While the equities of allowing Dr. Rosen to offer his full proposed panoply of opinions do weigh against Plaintiffs and do somewhat favor Covidien, Covidien did not seek at any time to have this Court review Magistrate Judge Majzoub's December 10, 2014 Order. The Court credits Covidien's explanation that it was not until Dr. Rosen's deposition had been taken that Covidien was able to appreciate the basis for objecting to that Order, but the Court is also cognizant of the fact that Dr. Rosen is Plaintiff's only expert on the issue of medical causation. Without Dr. Rosen's opinion on causation, Plaintiffs cannot submit any product liability theory to the jury, even assuming that they would be able to otherwise establish a *prima facie* case on one or more of their theories. *See Schaendorf v. Consumers Energy* Co., No. 281001, 2009 WL 563904, at *8 (Mich. Ct. App. March 5, 2009) ("expert testimony is indispensable to prove causation where 'it is to the scientific community that the law must look for the answer'") (quoting *Nelson v. American Sterlizer Co*., 223 Mich. App. 485, 489 (1997)); *Thomas v. Novartis Pharmaceuticals Corp*., 443 F. App'x 58, 63 (6th Cir. 2011) (finding that specific causation is "an essential element" of a products liability claim, and concluding that summary judgment was appropriately entered where plaintiff's treating physicians

were precluded from giving expert opinions regarding specific causation).

In light of the essential nature of Dr. Rosen's testimony in this matter and the early confusion over whether Dr. Rosen was required to file a Rule 26(a)(2)(B) Report in this case, and in view of the fact that this Court is unable to fully analyze the reliability of certain of Dr. Rosen's proffered opinions based on the parties' written submissions, the Court will GRANT the motion to strike certain portions of Dr. Rosen's testimony and will require Plaintiffs to present Dr. Rosen for examination at a *Daubert* hearing with regard to other portions of his proposed testimony, as discussed *infra*.

II. LEGAL STANDARD

"The Federal Rules of Evidence, the Federal Rules of Criminal and Civil Procedure and interpretive rulings of the Supreme Court and this court all encourage, and in some cases require, parties and the court to utilize extensive pretrial procedures-including motions in limine-in order to narrow the issues remaining for trial and to minimize disruptions at trial." *United States v. Brawner*, 173 F.3d 966, 970 (6th Cir. 1999). District courts have broad discretion over matters involving the admissibility of evidence at trial. *United States v. Seago*, 930 F.2d 482, 494 (6th Cir. 1991).

III. ANALYSIS

Even if permitted as properly within the scope of treatment, a treating physician's testimony remains subject to the requirement set forth in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 592 (1993), that an expert's opinion testimony must "have a reliable basis in the knowledge and experience of his discipline." *See Gass v. Marriott Hotel Servs., Inc.*, 558 F.3d 419, 426 (6th Cir. 2009) (noting that "a treating physician's testimony is still subject to the requirements of *Daubert*"); *Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 704-05 (7th Cir. 2015) ("Treating physicians are no

different than any other expert for purposes of Rule 702; before proffering expert testimony [as to causation], they must withstand *Daubert* scrutiny like everyone else.") (alteration added). *See also In re Aredia and Zometa Pdcts. Liab. Litig.*, 483 F. App'x 182, 187 (6th Cir. 2012) ([A] treating physician's testimony is subject to *Daubert*.").

Under *Daubert*, before allowing an expert's testimony to be considered by the jury, a trial court should consider: "'(1) whether the reasoning or methodology underlying the expert's testimony is scientifically valid; and (2) whether that reasoning or methodology properly could be applied to the facts at issue to aid the trier of fact.'" *Gass*, 558 F.3d at 426 (quoting *United States v. Smithers*, 212 F.3d 306, 315 (6th Cir. 2000)). "No matter how good experts' credentials may be, they are not permitted to speculate." *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 671 (6th Cir. 2010) (internal quotation marks, citation and brackets removed). An expert "may be a distinguished doctor, and his conjecture about causation may be worthy of careful attention . . . . but the courtroom is not the place for scientific guesswork, even of the inspired sort." *Id.* (internal quotation marks and citation omitted) (ellipsis in original). The Court must determine whether Dr. Rosen's knowledge and experience qualify him to render the opinions he proffers, whether those opinions will assist the trier of fact in understanding the evidence or help the trier of fact to determine a fact in issue and whether those opinions reliable. *Bradley v. Ameristep*, 800 F.3d 205 (6th Cir. 2015). "'Red flags that caution against certifying an expert include reliance on anecdotal evidence, improper extrapolation, failure to consider other possible causes, lack of testing, and subjectivity.'" *Dow v. Rheem Mfg. Co.*, 527 F. App'x 434, 437 (6th Cir. 2013) (quoting *Newell Rubbermaid Inc. v. Raymond Corp.*, 676 F.3d 521, 527 (6th Cir. 2012)).

To pass scrutiny under *Daubert*, Dr. Rosen's opinion that the crosslinking of Permacol caused Mr. Avendt's injuries must: (1) be based upon Dr. Rosen's scientific, technical, or other specialized knowledge, (2) be the product of reliable scientific principles and methods that are generally accepted in the scientific community, and (3) be reliably applied to the facts of this case. As to certain of Dr. Rosen's proffered opinions, the Court concludes that Plaintiffs clearly have failed to sustain their burden under *Daubert* and such testimony will be inadmissible in a trial in this matter. As to other of Dr. Rosen's proffered opinions, the Court finds both the reliability of those opinions and the reliability of their application in this case to be in doubt and concludes that a *Daubert* hearing is necessary to fully inform the Court's decision as to those opinions.

(1) ***Dr. Rosen lacks sufficient qualifications as to certain aspects of his proffered opinions and those opinions will be inadmissible in any trial in this matter.*** Dr. Rosen, although an eminently well qualified and respected clinician and surgeon, is unqualified by training and education to offer an expert opinion on the material or biomechanical science of crosslinking or on the body's immunological response to crosslinked materials. When deposed, Dr. Rosen could not explain the process by which Permacol is crosslinked, he did not understand the significance of using HMDI as a processing agent and he did not know whether Permacol was terminally ("like leather") or partially (more porous) crosslinked. Dr. Rosen, by his own admission, has no expertise in the material science of crosslinking, or the biomechanical aspects of mesh "fatigue and breakage." He testified that he has various biomaterial and biomechanical experts who collaborate on his papers who provide that area of expertise; his name is on the papers and he is conversant in it but he is not an expert. (Rosen Dep. 164:17:166:3). Dr. Rosen further conceded that he is no expert in the area of immunogenic response to crosslinked mesh, despite an in-depth treatment of the subject in a 2012

article that he co-authored, and testified that he collaborates with experts on that topic as well, but he doesn't think that "anybody knows exactly how the human body responds to any of these materials" (Rosen Dep. 80:23-82:8).

With regard to Dr. Rosen's purported "personal experience with Permacol prior to Plaintiff's surgery," Dr. Rosen's deposition revealed that he had NO personal experience with Permacol prior to Mr. Avendt's surgery. Dr. Rosen concedes that he is not the scientist who vetted the design of Permacol, and he never reviewed the testing or design background on Permacol. Dr. Rosen never used Permacol, he never touched a piece of Permacol prior to Plaintiff's surgery, and he could not speak to the specifics of the process by which Permacol was designed or tested.

There is no doubt that Dr. Rosen is a highly respected clinician and surgeon in the field of abdominal wall reconstruction. And his name appears on numerous peer reviewed publications addressing various aspects of the study of various synthetic and biologic mesh products. But Dr. Rosen concedes that he relies on other "experts" on the topics of the material science of crosslinking, the immunological response of the body to crosslinked mesh products and concedes that he has no knowledge regarding design and testing as related specifically to Permacol. While he may be a renowned clinician and surgeon, and even a great "teacher," as Plaintiffs represent, he lacks sufficient expertise to opine on the topics of the material science of crosslinking, immunogenic response to crosslinked material or the scientific process related to the fatigue and breakdown of mesh. Similarly unsupported are any opinions relating specifically to the design and testing of Permacol. The Defendant's motion to strike all such opinions is GRANTED without need of a *Daubert* hearing.

(2) ***A Daubert hearing is required to determine whether Dr. Rosen's opinions are sufficiently reliable, i.e. whether they are generally accepted in the general medical community or even by Dr. Rosen himself.*** Despite his admitted lack of scientific expertise in the material science of crosslinking and the body's immunogenic response to Permacol, Plaintiffs seek to have Dr. Rosen opine to the jury, presumably based on his clinical and surgical experience, that Permacol "behaved like a synthetic mesh," and was therefore not fit to be sold (or at least not unaccompanied by some more robust warnings) for placement in a clean-contaminated (Class II) wound. An expert may be qualified by personal knowledge and experience, but such "experience-based" testimony must be the product of "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael,* 526 U.S. 137, 152 (1999). The Court concludes that it has insufficient evidence to determine whether Dr. Rosen's experience-based opinion is reliable, i.e. generally accepted in the medical community or even by Dr. Rosen himself, and therefore there is doubt whether it would be relevant and helpful to a jury in this case. Consequently, a *Daubert* hearing will be necessary to resolve this critical issue.

Although Dr. Rosen purports to offer the opinion, one that he purportedly held in 2010 when he performed Mr. Avendt's surgery, that the crosslinking of Permacol made it inappropriate for placement in a Class II wound and caused Mr. Avendt to have a chronic, non-healing infected wound which resulted in his injuries, Dr. Rosen's 2009 article reviewing reported adverse events in the MAUDE database appears to contradict this opinion. That article concedes that the effects of crosslinking on wound healing in the case of contaminated wounds (Class III) were "largely unknown," but that crosslinked meshes, such as Permacol, appeared to perform "reasonably well" in clean (Class I) and clean contaminated (Class II) wounds:

> The complexities of a contaminated wound, implantation of any foreign body (even if biologic), and its outcome on wound healing is largely unknown. . . . Based on the available literature and the review of the FDA MAUDE database, it seems reasonable to conclude that cross-linked meshes seem to behave reasonably well in clean and clean contaminated cases; however, the effect of cross-linking on infected and contaminated ventral hernia repair remains largely unknown at this time and requires careful evaluation.

ECF NO. 159-3, Major Complications Associated With Xenograft Biologic Mesh Implantation in Abdominal Wall Reconstruction, Surgical Innovation, http://sri.sagepub.com/content/16/4/324.

Dr. Rosen revealed at his deposition that he was not aware at the time he performed Mr. Avendt's surgery what Mr. Avendt's wound classification was when the Permacol mesh was implanted. The evidence reveals that the wound was either Class I (clean) (Plaintiffs' version of the facts) or Class II (clean contaminated) (Dr. Ash's and Defendant's version of events) and thus, according to Dr. Rosen's 2010 published article, the Permacol ought to have performed "reasonably well" for Mr. Avendt. Thus, Dr. Rosen's published opinion at the time he performed Mr. Avendt's surgery was that crosslinked meshes behave "reasonably well in clean and clean contaminated cases" but that the effects of repairing hernias with crosslinked mesh were "largely unknown" and required further study.

Subsequently, in 2012, Dr. Rosen co-authored another article that studied 116 case reports, "85% were in noncontaminated or clean-contaminated cases and 15 percent were in infected and contaminated cases." ECF No. 159, Pls.' Resp. Ex. D, The Biology of Biologics, p. 13S-14S. The results of the study indicated that Permacol "behave[s] reasonably well" in the first two categories but that "the effect of cross-linking on infected and contaminated ventral hernia repair remains largely unknown at the time and requires careful evaluation." Again, in 2014, Dr. Rosen co-authored an article entitled "Abdominal Wall Reconstruction," Current Problems in Surgery, 50

(2013) 557-586, 565, which concluded that a group of biologic mesh products, including Permacol, "appear to tolerate placement in a clean-contaminated field."

Finally, Plaintiffs propose to have Dr. Rosen testify that Permacol "behaves like a synthetic mesh," and that because of this propensity it was either defective or Covidien failed to warn of this fact. The evidence establishes that Permacol is "partially" and not "terminally, heavily or highly" crosslinked, as are other biologic meshes such as Collamend. Dr. Rosen did not know the process by which Permacol was crosslinked and did not profess to understand the different processes by which various biologic meshes are crosslinked; he could not explain the material science aspects of partial versus terminal crosslinking. Defendant's experts, Dr. Williams and Dr. Dunn, explained that the HMDI product used to partially crosslink Permacol is designed to allow for a favorable and reasonable pace of integration, as opposed to highly crosslinked materials which allow for a slower pace of cell infiltration. Def.'s Mot. Ex. D, Dunn Dep. 61:5-62:19, 66:22-12. As Dr. Rosen explained, in general the quicker the ingrowth or cell integration, the more resistant the material becomes to bacterial colonization. Rosen Dep. 73:13-25. In his 2012 article, Dr. Rosen and his co-authors appear to have confirmed this distinction between the characteristics of partially and heavily crosslinked biologics, concluding that Collamend, a "heavily crosslinked" biologic, "behaved similar to a synthetic mesh given the heavy cross-linking," and recommended against its use in any instance of abdominal wall reconstruction. ECF No. 159, Ex. D, The Biology of Biologics 14S. Tellingly, no such observation was made by the authors with respect to Permacol, which performed reasonably well in clean and clean contaminated cases but needed "careful evaluation" of its performance in contaminated and infected cases, the results of which were "largely unknown" at the time of publication in 2012. *Id.* Because the authors conclude that Collamend, a heavily crosslinked

biologic, performs "like a synthetic," but make no such observation, indeed suggest no such property, with respect to Permacol, Dr. Rosen's own research appears to undercut Plaintiffs' central claim that Permacol, a partially crosslinked mesh, "behaves like a synthetic."

In part because Dr. Rosen did not file a Rule 26(a)(2)(B) Report in this case, Defendant was not able to examine Dr. Rosen at the time of his deposition about these seeming inconsistencies between the opinion that Plaintiffs seek to have him offer in this case and his own published works. When asked at his deposition whether there were any studies to his knowledge that showed success with Permacol, Dr. Rosen responded that there were only "very flawed studies" that showed success. Rosen Dep. 124:22-125:7. He testified that he was unaware of any articles that state that Permacol is safe and effective in a Class II wound. *Id*. at 171:11-14. Yet his own published articles available at the time showed Permacol performing "reasonably well," and "tolerating placement," in a Class II wound. This case presents at worst a Class II wound. Defendant and the Court must have an opportunity to explore these apparent inconsistencies before concluding that Dr. Rosen's opinions possess sufficient reliability to be placed before a jury for consideration.

When Dr. Rosen operated on Mr. Avendt in January, 2010, he discovered remnants of Permacol mesh in a Class IV infected wound. There is no evidence in this case, however, that Permacol was placed, or left, in an overtly infected or contaminated (Class III or IV) wound. Plaintiffs' theories in this case appear to be grounded in the factual premise, which they seek to place before the jury based on Dr. Rosen's testimony, that Permacol should not have been available to Dr. Ash to use when he suspected a possible Class II (clean contaminated) operative site, or that the Permacol IFU should have warned Dr. Ash either that he should not place Permacol in a suspected Class II wound or should have instructed Dr. Ash to remove Permacol in the presence of

a suspected infection.[2] There is insufficient evidence in the record for the Court to conclude that such opinions are generally accepted in the medical community or even by Dr. Rosen himself. A *Daubert* hearing will be necessary so that Defendant, and the Court, can examine Dr. Rosen further on these opinions.

(3) ***A Daubert hearing is required to determine whether Dr. Rosen's opinion that the crosslinking of Permacol caused Mr. Avendt's injuries in this case is the product of the reliable application of such methodology in this case.*** Dr. Rosen's opinion that the crosslinking of Permacol caused Mr. Avendt's injuries in this case, even if he is qualified to render it and assuming it is based upon generally accepted reasoning or methodology, will be unhelpful to a jury in understanding a disputed fact in this action, and therefore irrelevant and inadmissible, if Dr. Rosen's application of such an opinion to the facts of this case is unreliable.

Dr. Rosen supplies the following explanation for his opinion that crosslinking of Permacol caused Mr. Avendt's injuries:

> Q: So in terms of what was your methodology in coming to your conclusion of the case that it was the crosslinking that –
>
> A: Sure. So my hypothesis was, he had a chronic draining sinus because there was a piece of foreign material in there, Permacol. So my observation was that the wound did not heal for a year. In my experience in maybe managing 2 to 3,000 of these cases, typically when wounds don't heal, there's some remaining foreign body

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[2] While the Court is not addressing Defendant's summary judgment motion in this Opinion and Order, these theories are perplexing in view of Plaintiffs' revelation at the hearing on this matter that according to their version of the facts, Dr. Ash actually placed Permacol in a Class I Clean wound when he operated on Mr. Avendt in December, 2008, and that Mr. Avendt showed no sign of infection subsequently in May, 2009, when Dr. Ash reoperated on Mr. Avendt to drain a seroma. Because even Plaintiffs' proposed expert, Dr. Rosen, has testified that Permacol is safe and effective (although expensive) for placement in a Class I clean wound, the Court struggles to understand how Plaintiffs can succeed on any theory of product defect in this case. Having taken this position openly and adamantly at oral argument, and having suggested such a position in their written submissions, Plaintiffs will not be permitted to pivot away from this factual position in this action.

> that the body cannot clear.
>
> So when we operated on him and performed the experiment, we drilled down and actually were able to observe and document unincorporated Permacol crosslinked mesh sitting in a bed of puss [sic] and granulation tissue due to ongoing nonhealing. And when we removed it all, you know, my conclusion, even in the setting of contamination, the wound healed. So to me that's conclusive, that for one year the wound didn't heal, you take out the one thing and everything heals from an infectious standpoint, to me, that's pretty good scientific evidence that it's conclusive.

Rosen Dep. 174:17-175:16.

In a 2012 article co-authored by Dr. Rosen, examining the performance of various biologic products including Permacol, the authors conclude that "biologic mesh is a promising adjunct to the construction of abdominal wall defects," but that further study is needed and that it is "imperative that authors report accurately on patients who are receiving these grafts, including the comorbidities, wound classification, and hernia grades, to allow appropriate pooling of data." (Pls.' Resp. Ex. D, The Biology of Biologics at 16S.)

Comorbidities, wound classification, hernia grade – imperative data in determining the effects of crosslinking, according to Dr. Rosen's own published opinions and his deposition testimony in this case. Yet there is no evidence that Dr. Rosen considered any one of these factors in forming his opinion that Permacol caused Mr. Avendt's chronic nonhealing wound in this case. Dr. Rosen did not know the wound classification into which Dr. Ash placed the Permacol and there was nothing in his operative note that revealed he ever considered the initial wound classification, Rosen Dep. 98:8-13, Def.'s Mot. Ex. N, nor did he consider the wound classification at the time that Dr. Ash elected to leave the Permacol in place in May, 2009. All Dr. Rosen knows, and all he knew at the time he operated on Mr. Avendt in 2010, was that the wound was infected (Class IV) and that pieces of the Permacol remained in the wound. Dr. Rosen did not consider whether Mr. Avendt's

morbid obesity or his diabetes or his three prior failed hernia repairs, all factors that Dr. Rosen concedes affect the ability of the body to heal and that Dr. Rosen considers "imperative" to an understanding of the effects of crosslinking, had any effect on his body's inability clear the infection:

> Q: Did Mr. Avendt's past medical history have an impact on his ability to heal?
>
> A: Based on what I said before, I don't know what his glucose control was. I'd have to know that to specifically answer that. Did I say what his BMI was here? I didn't say what his BMI was, so it's hard to specifically say how obese he was at the time. So I don't know if I can give you a complete answer on that.
>
> Q: Do you have any opinion on whether or not Mr. Avendt has difficulty healing?
>
> A: Just in general or –
>
> Q: Yes sir.
>
> A: No.
>
> Q: You do not have an opinion?
>
> A: I would need to get more information. I mean, if I know what his HbA1c is, what his glucoses were and what his actual BMI is, you know, I would probably be able to answer that.
>
> Q: And we can't tell that from this record. Is that correct?
>
> A: Not from my note.

Rosen Dep. 93:12-21. 94:12-25. In fact, none of Dr. Rosen's records revealed that he had obtained the answers to any of these questions in the course of his treatment of Mr. Avendt or subsequently when he formed the opinions that Plaintiffs seek to offer in this case.

It appears that Dr. Rosen never considered whether Mr. Avendt, unburdened by these significant comorbidities and three prior failed hernia repairs, may have had a different immunogenic response to the Permacol implant that would have prevented seroma formation or

adequately cleared an infection. There is no evidence that Dr. Rosen gathered or considered this "imperative" data in allegedly forming the opinion that it was the crosslinking of Permacol that caused Mr. Avendt's injuries. Dr. Rosen concedes that obesity is a major complication with any hernia repair and in fact he "prefers" not to operate on obese patients: "I prefer not to operate on obese patients. I mean, I'll be clear on that. . . . It's technically harder, they have more tissues. Whether it results in longer term more failures, I'm not a hundred percent sure, but certainly shorter term more issues." Rosen Dep. 45:8-16. Dr. Rosen described Mr. Avendt as "an obese individual" yet never determined his BMI, Rosen Dep. 188:16-18, or considered the effect that Mr. Avendt's obesity may have had on his inability to heal in this particular case.

Dr. Rosen explains that he suspected that a foreign material (Permacol) was present in the hernia wound that Mr. Avendt could not clear, that the operation bore this theory out and that when he removed the foreign material he confirmed that it was Permacol and after removal the wound healed. Form this data alone, Dr. Rosen concludes that the crosslinking of Permacol was the cause of Mr. Avendt's chronic inability to heal. Dr. Rosen failed to consider three of the most "imperative" factors, each of which Mr. Avendt presented with, to understanding the causal effects of the Permacol mesh on Mr. Avendt's wound healing capabilities in this case. Plaintiffs bear the burden of presenting sufficient evidence that Dr. Rosen's opinion that Permacol was the cause of Mr. Avendt's injury is the "'product of reliable principles and methods . . . applied . . . reliably to the facts of the case.'" *Tamraz*, 620 F.3d at 670 (citing Fed. R. Evid. 702).

"[A] treating physician needs to be able to distinguish the causes of the disease." *Thomas*, 443 F. App'x at 63 (treating physician, although an eminently qualified and respected surgeon, could not give testimony regarding causation/etiology) (alteration added). *See also In re Aredia and*

Zometa Pdcts. Liab. Litig., 483 F. App'x 182, 188-89 (6th Cir. 2012) (holding that district court properly excluded treating physician's expert opinion on causation where the treating physician conceded that "the current level of evidence does not fully support [the] cause-and-effect relationship" that he proffered and his knowledge and experience did not otherwise qualify him to opine as to the specific etiology of plaintiff's condition); *Amerson v. Stechly*, No. 12-10375, 2015 WL 6436341 (E.D. Mich. Oct. 22, 2015) (where treating physician did not testify that he considered alternative causes consistent with Plaintiff's symptoms or that he employed any method to determine alternative causes were less likely, his testimony was excluded under 702). "The ability to diagnose medical conditions is not remotely the same . . . as the ability to deduce . . . in a scientifically reliable manner, the causes of those medical conditions." *Tamraz*, 620 F.3d at 673. "Doctors thus may testify to both, but the reliability of one does not guarantee the reliability of the other." *Id*. at 674.

The Court does not doubt that Dr. Rosen is eminently qualified in his field and acknowledges his collaboration with a field of other experts to study the performance of crosslinked biologic mesh products in abdominal hernia repairs. Dr. Rosen obviously is not a "fan" of crosslinking and believes that the field merits further study. However, Plaintiffs have not provided sufficient evidence for the Court to conclude that Dr. Rosen has reliably applied a generally accepted methodology in reaching his "opinion" that, because he discovered a piece of Permacol in Mr. Avendt's infected wound and after he removed it the infection cleared, Permacol's crosslinking caused Mr. Avendt's chronic inability to heal and related injuries in this case. A *Daubert* hearing will be necessary so that Defendant, and the Court, can examine Dr. Rosen further on these opinions.

IV. CONCLUSION

For the foregoing reasons, the Court GRANTS IN PART Defendant's Motion to Limit the Testimony and Opinion of Dr. Michael Rosen. At any trial in this action, Dr. Rosen will be precluded from offering any testimony or opinion regarding: (1) the material science of crosslinking in general or of the design and testing of Permacol in specific; or (2) the immunogenic response of the body to crosslinked biologic mesh products or other aspects of the science of mesh fatigue and breakdown.

Dr. Rosen's proffered opinion that the crosslinking of Permacol caused Mr. Avendt's chronic nonhealing wound and resultant injuries in this case requires further exploration at a *Daubert* hearing. It is not possible for the Court to conclude based solely upon the parties' written submissions and the oral argument that took place on December 22, 2015, whether Dr. Rosen's opinion is simply too unreliable to be helpful to the jury or whether his opinion is one that ought to be admitted and tested through the crucible of cross-examination. The parties shall consult among themselves, and with Dr. Rosen's schedule, and shall provide the Court with three alternative dates on which Dr. Rosen would be available to appear in Court for a *Daubert* hearing. The Court will then consult its own calendar and will notify the parties of the hearing date.

IT IS SO ORDERED.

s/Paul D. Borman
PAUL D. BORMAN
UNITED STATES DISTRICT JUDGE

Dated: April 19, 2016

CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing order was served upon each attorney or party of record herein by electronic means or first class U.S. mail on April 19, 2016.

s/Deborah Tofil
Case Manager